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ARNOLD & PORTER

202.942.5000
202.942.5999 Fax
555 Twelfth Street, NW
Washington, DC 20004-1206

December 1, 2003

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Application No. 09/819,091
Filed: February 16, 2000
Title: Plant Genome Sequences and Uses Thereof
Applicants: CAO *et al.*
Atty. Docket: 16517.124

Sir:

The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office (PTO):

1. an Appellant's Brief (in triplicate); and
2. a return postcard.

Please stamp the attached postcard with the filing date of these documents and return it to our courier.

Applicants request that the following fee be charged to Deposit Account No. 50-2387 referencing docket number 16517.124:

$ 330.00 appeal brief fee

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any fees, other than the above fee ($330), are due in conjunction with this filing. However, if any additional fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter Deposit Account No. 50-2387 referencing matter number 16517.124. A duplicate copy of this letter is enclosed.

Respectfully submitted,

David R. Marsh (Reg. Attorney No. 41,408)
Holly Logue Prutz (Reg. Attorney No. 47,755)

Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:	
Yongwei CAO *et al.*	Art Unit: 1634
Appl. No.: 09/819,091	Examiner: A. Chakrabarti
Filed: February 16, 2000	Atty. Docket: 16517.124
For: Plant Genome Sequences and Uses Thereof	

APPELLANT'S BRIEF

Attn: Mail Stop Appeal Brief-Patent

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an Appeal from the final rejection of all claims pending in the above-described patent application. A Notice of Appeal was filed on October 1, 2003. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Applicants are unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1-3 and 8-11 are pending. Claims 2-3 and 8-11 stand finally rejected under 35 U.S.C. § 112, first paragraph. Claims 1-3 and 8-11 stand finally rejected under 35 U.S.C. § 101.

Claims 2-3 and 9-11 stand finally rejected under 35 U.S.C. § 112, first paragraph. Applicants appeal all of the rejections of each of the claims.

4. Status of Amendments

Applicants have not filed any responses subsequent to the Final Office Action mailed July 1, 2003 ("Final Action") in this case.

5. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1 or its complement. Specification page 19, lines 23-25, and claim 1 as originally filed. The invention is also directed to a substantially purified nucleic acid molecule capable of specifically hybridizing to a second nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1 or its complement. Specification page 12, lines 21-24 and claim 2 as originally filed. The invention is also directed to a substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% identity to a nucleic acid sequence of SEQ ID NO: 1 or complement thereof. Specification page 19, line 25 through page 20, line 12.

6. Issues

The issues in this Appeal are:

(a) whether claims 2-3 and 8-11 are unpatentable under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description;

(b) whether claims 1-3 and 8-11 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by either a specific and/or substantial utility or a well established utility; and

(c) whether claims 2-3 and 9-11 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because the claimed invention purportedly lacks utility.

7. Grouping of Claims

All of the claims at issue do not stand or fall together. The patentability of claims 2-3 and 8-11 is addressed in Sections 9.A and 9.B below. The separate patentability of claims 1-3 and 8-11 is addressed in Sections 9.A and 9.C below. The separate patentability of claims 2-3 and 9-11 is addressed in Sections 9.A and 9.D below. A copy of the claims on appeal is attached hereto as Appendix A.

8. Preliminary Remarks

Applicants thank the Examiner for withdrawing the rejections of claims 3-7 under 35 U.S.C. § 112, second paragraph, and under 35 U.S.C. § 102(a).

9. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility . . . where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, as a genetic marker or to identify a polymorphism. These benefits are specific, not vague or unknown, and they are "real world" or substantial benefits. Because the claimed nucleic acid molecules provide at least these benefits, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acids for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicants have provided an adequate description of the claimed nucleic acid molecules that demonstrates Applicants' possession of the claimed invention. The genera of claimed nucleic acid molecules, for example, the genus of nucleic acid molecules comprising the

nucleic acid sequence of SEQ ID NO: 1, have been described by the recitation of common structural features, *e.g.*, the nucleotide sequence of SEQ ID NO: 1, which distinguishes molecules in the claimed genus from molecules not in the claimed genus. Because the specification demonstrates that Applicants had possession of (and have provided an adequate description of) the claimed genera of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

B. The Specification Provides an Adequate Written Description of the Claimed Invention

Despite the Examiner's admission that the sequence of SEQ ID NO: 1 meets the written description provision of 35 U.S.C. § 112, first paragraph (Final Action at page 2), the adequacy of the written description of claims 2-3 and 8-11 has been challenged by the Examiner because the claimed subject matter was allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Final Action at page 2. The basis for the Examiner's challenge is that the claims are directed to "encompass gene sequences, sequences that hybridize to SEQ ID NO: 1, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, and homologous sequences, and so forth.... The specification provides insufficient written description to support the genus encompassed by the claim." Final Action at pages 2-3. This is not a proper basis for a written description rejection of a "comprising" claim. If it was, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules.

(1) The Specification Reflects Applicants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if every nuance of the invention was not expressly described, then the written description requirement has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. After reading the present specification, a person of ordinary skill in the art would understand that Applicants had possession of nucleic acid molecules comprising SEQ ID NO: 1, molecules that are capable of specifically hybridizing to the claimed nucleic acid molecules, or that share a claimed identity to SEQ ID NO: 1, complements thereof, and proteins encoded by the claimed nucleic acid molecules, and therefore, the claimed invention.

Applicants have provided the nucleic acid sequence required by the claims, *i.e.*, SEQ ID NO: 1, as well as, for example, vectors comprising the nucleic acid sequence (*see, e.g.,* specification at page 61, line 1 through page 69, line 7), and hybridization conditions which may be used with the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 18, line 9 through page 19, line 22). The fact that the claims at issue are intended to cover, for example, molecules that include the recited sequence joined with additional sequences does not mean that Applicants were any less in possession of the claimed nucleic acid molecules.[1] It is well-established that use of the transitional term "comprising" leaves the claims "open for the

1 If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then she goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

Applicants have provided in the present disclosure not only the nucleotide sequence required by the claims (*i.e.* SEQ ID NO: 1), but also several variations including and directed to the claimed nucleic acid molecules. For example, the present specification describes vectors comprising the claimed nucleic acid molecules (specification at page 61, line 1 through page 69, line 7), and describes how to make the nucleotide sequences and libraries from which they were originally purified. *See, e.g.*, Examples page 95, *et seq*. Furthermore, the addition of extra nucleotides or detectable labels to the disclosed nucleotide sequence (SEQ ID NO: 1) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[2] for example, at page 34, line 18 through page 35, line 13 (describing fusion peptide molecules encoded by the claimed nucleic acid molecules), page 18 lines 1-5 (describing sequences with labels to facilitate detection), page 60, lines 3-27 (describing site-directed mutagenesis), page 18, line 9 through page 19, line 18 (describing appropriate hybridization conditions for the claimed nucleic acid molecules), and page 81, lines 11-19 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules).

Moreover, the court determined, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 U.S.P.Q.2d 1609, 1610 (Fed. Cir. 2002), that the written description inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art." *Enzo*, 296 F.3d at 1326-1327, 63 U.S.P.Q.2d at 1615. It is well established that

2 It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

claims "may be broader than the specific embodiment disclosed in a specification. *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In reRasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

(2) Applicants Have Described the Claimed Invention

The Final Action asserts "[T]he species specifically disclosed are not representative of the genus because the genus is highly variant." Final Action at page 5. The Examiner appears to assert that each nucleic acid molecule within the claimed genus must be described by its complete structure. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

In particular, Applicants have disclosed structural features, for example, the nucleotide sequence of SEQ ID NO: 1. The respective structural feature (the nucleotide sequence of SEQ ID NO: 1) is shared by every nucleic acid molecule in the claimed genus, and it distinguishes the members of the claimed genus from non-members. For example, if a nucleic acid molecule such as an mRNA is capable of hybridizing to a nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules capable of specifically hybridizing to a nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1.[3] If a nucleic acid molecule is not capable of hybridizing to a nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1, then it is not a member of the claimed genus. The

3 The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule such as an mRNA contains a nucleic acid molecule having 90% identity to a nucleic acid sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence having 90% identity to a nucleic acid sequence of SEQ ID NO: 1. *See* claim 8.

presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either hybridizes to a nucleic acid molecule having the nucleotides of SEQ ID NO: 1 or it does not. One skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains the recited nucleotide sequence. Thus, claims 2-3 and 8-11 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

The Examiner also argues that "[n]either the specification nor the claims disclose any structure-function relationship." Final Action at page 5. Applicants are aware of no such requirement to satisfy written description under 35 U.S.C. § 112, first paragraph. To the contrary, the Federal Circuit, in *Moba B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320, 66 U.S.P.Q.2d 1429, 1438 (Fed. Cir. 2003), the Federal Circuit clarified that a "court should determine whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants and mixtures sufficient to demonstrate possession of the generic scope of the claims." *Moba* at 10, *citing Enzo Biochem, Inc. v. Gen-Probe, Inc.* 323 F.3d 956, 966, 63 U.S.P.Q.2d 1609, 1615 (Fed. Cir. 2002). The Federal Circuit also reiterated that "[t]he test for compliance with §112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filling." *Moba* at 10. Moreover, in the present case, Applicants have described the claimed nucleic acid molecules by "structural features commonly possessed by members of the genus that distinguishes them from others." *Eli Lilly* at 1568-69.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule is capable of specifically hybridizing to a nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1. Thus, the claims are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112.

C. The Claimed Nucleic Acids Have Legal Utility

Claims 1-3 and 8-11 were erroneously rejected under 35 U.S.C. § 101 as allegedly not supported by a "specific, substantial, and credible utility or by a well established utility." Final Action at page 2. The Examiner admits that the specification discloses that the nucleic acid molecules of the present invention, including "probes for assisting in the isolation of full-length cDNAs or genes which would be used to make protein and optionally further usage to make the corresponding antibodies, gene mapping, isolation of homologous sequences, detection of gene expression such as in Northern blot analysis, molecular weight markers, chromosomal markers,...for numerous other generic genetic engineering usages, expression, antibody production,...detection of expression, antibody production, Western blots, etc." Final Action at page 7. However, the Final Action asserts these utilities are not a "specific and/or substantial utility or a well-established utility." Final Action at page 7.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip*, 185 F.3d at 1366, 51 USPQ.2d at 1702. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real

world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example, use to identify the presence or absence of a polymorphism, and use as a hybridization probe for expression profiling. *See, e.g.*, specification at page 56, line 25, through page 57, line 23 and at page 45, line 24, through page 56, line 24. Either of these utilities described alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including isolating full-length cDNAs or genes, gene mapping, detection of gene expression, and as molecular weight markers. *See* Final Action at page 7. Moreover, the specification also discloses additional utilities for the claimed nucleic acid molecules,[4] including use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,[5] and use as molecular markers.[6]

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4 It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

5 It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest.

6 One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular

(a) Identifying the Presence or Absence of a Polymorphism

One of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 49, line 24 through page 56, line 24. The Examiner argues that this utility, like many of the asserted utilities, is not specific or substantial, *see, e.g.,* Final Action at page 7, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms using the claimed nucleic acid molecules is not a legal utility.

Many of the disclosed utilities in this case, including the detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates such utilities by asserting that these utilities are not "useful" because they are "generic in nature" and, allegedly, "[i]dentifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a 'real world' context or use." Final Action at page 8. However, the fact that, *e.g.*, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107.01 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself.

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markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

Information has been obtained about the gas.[7] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The Examiner suggests that these uses are not legal utilities because "...[n]either the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well-established for the compounds." Final Action at pages 8-9. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used to isolate nucleic acid molecules of other plants and organisms such as alfalfa, barley, *Brassica*, soybean, sunflower, *Phaseolus*, etc.[8] Specification at page 34, line 25 through page 35, line 13. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and thus has not met the burden of proof required to establish a utility rejection. *See In re Brana*,

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7 For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

8 Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be isolated using a claimed nucleic acid molecule is the promoter of the gene corresponding to that claimed nucleic acid molecule. Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. Specification at page 47, line 18, through page 48, line 23. The Examiner denigrates that utility by asserting that it is not "specific to the nucleic acid(s) and/or protein(s) being claimed." Final Action at page 8. This is not correct. The claimed nucleic acid molecules are particularly useful, for example, to identify markers and isolate promoters in *Arabidopsis*. *See, e.g.*, specification at page 85 *et. seq.* (Example 1).

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose, *i.e.,* chromosome walks. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acid molecules. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter active in *Arabidopsis*. *See, e.g.*, specification at page 1, line 20 through page 2, line 2; page 23, lines 6-27; and Example 1 at

page 85, line 24, *et. seq.* A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a better starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

The Final Action also appears to assert that the disclosed uses are legally insufficient because they are not "substantial" utilities. Final Action at pages 7-9. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). " 'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[9]

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an

9 *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

immediate benefit to the public because, *e.g.*, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Cf. Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 2107 at 2100-29. Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[10]

10 Examples of incredible utilities are given in MPEP § 2107.01 at page 2100-34, and include:

A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2107.02 at 2100-41.

Applicants have explicitly identified specific and substantial utilities, not only in the specification, but in Applicants' Response dated May 19, 2003, at page 13, for example. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 1 under 35 U.S.C. §101 is improper and should be reversed.

D. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claims 2-3 and 9-11 were erroneously rejected as not enabled by the specification, because the claimed

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an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 9. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

Date: December 1, 2003

Holly L. Prutz
(Registration No. 47,755)
David R. Marsh
(Registration No. 41,408)

Of Counsel
Lawrence M. Lavin, Jr.
(Registration No. 30,768)
Thomas E. Kelley
(Registration No. 29,938)
Monsanto Company

ARNOLD & PORTER
555 Twelfth Street, NW
Washington, DC 20004-1206
202.942.5000 telephone
202.942.5999 facsimile

APPENDIX A

1. A substantially purified nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1 or its complement.

2. A substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing to a second nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1 or its complement.

3. A substantially purified *Arabidopsis thaliana* protein encoded by a molecule of claim 2.

8. A substantially purified nucleic acid molecule, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 90% identity to a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

9. The substantially purified nucleic acid molecule according to claim 8, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 95% identity to a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

10. The substantially purified nucleic acid molecule according to claim 9, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 98% identity to a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

11. The substantially purified nucleic acid molecule according to claim 10, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 99% identity to a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:	
Yongwei CAO *et al.*	Art Unit: 1634
Appl. No.: 09/819,091	Examiner: A. Chakrabarti
Filed: February 16, 2000	Atty. Docket: 16517.124
For: Plant Genome Sequences and Uses Thereof	

APPELLANT'S BRIEF

Attn: Mail Stop Appeal Brief-Patent

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an Appeal from the final rejection of all claims pending in the above-described patent application. A Notice of Appeal was filed on October 1, 2003. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Applicants are unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1-3 and 8-11 are pending. Claims 2-3 and 8-11 stand finally rejected under 35 U.S.C. § 112, first paragraph. Claims 1-3 and 8-11 stand finally rejected under 35 U.S.C. § 101.

Claims 2-3 and 9-11 stand finally rejected under 35 U.S.C. § 112, first paragraph. Applicants appeal all of the rejections of each of the claims.

4. Status of Amendments

Applicants have not filed any responses subsequent to the Final Office Action mailed July 1, 2003 ("Final Action") in this case.

5. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1 or its complement. Specification page 19, lines 23-25, and claim 1 as originally filed. The invention is also directed to a substantially purified nucleic acid molecule capable of specifically hybridizing to a second nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1 or its complement. Specification page 12, lines 21-24 and claim 2 as originally filed. The invention is also directed to a substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% identity to a nucleic acid sequence of SEQ ID NO: 1 or complement thereof. Specification page 19, line 25 through page 20, line 12.

6. Issues

The issues in this Appeal are:

(a) whether claims 2-3 and 8-11 are unpatentable under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description;

(b) whether claims 1-3 and 8-11 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by either a specific and/or substantial utility or a well established utility; and

(c) whether claims 2-3 and 9-11 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because the claimed invention purportedly lacks utility.

7. Grouping of Claims

All of the claims at issue do not stand or fall together. The patentability of claims 2-3 and 8-11 is addressed in Sections 9.A and 9.B below. The separate patentability of claims 1-3 and 8-11 is addressed in Sections 9.A and 9.C below. The separate patentability of claims 2-3 and 9-11 is addressed in Sections 9.A and 9.D below. A copy of the claims on appeal is attached hereto as Appendix A.

8. Preliminary Remarks

Applicants thank the Examiner for withdrawing the rejections of claims 3-7 under 35 U.S.C. § 112, second paragraph, and under 35 U.S.C. § 102(a).

9. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility . . . where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, as a genetic marker or to identify a polymorphism. These benefits are specific, not vague or unknown, and they are "real world" or substantial benefits. Because the claimed nucleic acid molecules provide at least these benefits, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acids for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicants have provided an adequate description of the claimed nucleic acid molecules that demonstrates Applicants' possession of the claimed invention. The genera of claimed nucleic acid molecules, for example, the genus of nucleic acid molecules comprising the

nucleic acid sequence of SEQ ID NO: 1, have been described by the recitation of common structural features, *e.g.*, the nucleotide sequence of SEQ ID NO: 1, which distinguishes molecules in the claimed genus from molecules not in the claimed genus. Because the specification demonstrates that Applicants had possession of (and have provided an adequate description of) the claimed genera of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

B. The Specification Provides an Adequate Written Description of the Claimed Invention

Despite the Examiner's admission that the sequence of SEQ ID NO: 1 meets the written description provision of 35 U.S.C. § 112, first paragraph (Final Action at page 2), the adequacy of the written description of claims 2-3 and 8-11 has been challenged by the Examiner because the claimed subject matter was allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Final Action at page 2. The basis for the Examiner's challenge is that the claims are directed to "encompass gene sequences, sequences that hybridize to SEQ ID NO: 1, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, and homologous sequences, and so forth.... The specification provides insufficient written description to support the genus encompassed by the claim." Final Action at pages 2-3. This is not a proper basis for a written description rejection of a "comprising" claim. If it was, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules.

(1) The Specification Reflects Applicants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if every nuance of the invention was not expressly described, then the written description requirement has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. After reading the present specification, a person of ordinary skill in the art would understand that Applicants had possession of nucleic acid molecules comprising SEQ ID NO: 1, molecules that are capable of specifically hybridizing to the claimed nucleic acid molecules, or that share a claimed identity to SEQ ID NO: 1, complements thereof, and proteins encoded by the claimed nucleic acid molecules, and therefore, the claimed invention.

Applicants have provided the nucleic acid sequence required by the claims, *i.e.*, SEQ ID NO: 1, as well as, for example, vectors comprising the nucleic acid sequence (*see, e.g.*, specification at page 61, line 1 through page 69, line 7), and hybridization conditions which may be used with the nucleic acid molecules of the present invention (*see, e.g.*, specification at page 18, line 9 through page 19, line 22). The fact that the claims at issue are intended to cover, for example, molecules that include the recited sequence joined with additional sequences does not mean that Applicants were any less in possession of the claimed nucleic acid molecules.[1] It is well-established that use of the transitional term "comprising" leaves the claims "open for the

1 If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then she goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

Applicants have provided in the present disclosure not only the nucleotide sequence required by the claims (*i.e.* SEQ ID NO: 1), but also several variations including and directed to the claimed nucleic acid molecules. For example, the present specification describes vectors comprising the claimed nucleic acid molecules (specification at page 61, line 1 through page 69, line 7), and describes how to make the nucleotide sequences and libraries from which they were originally purified. *See, e.g.*, Examples page 95, *et seq*. Furthermore, the addition of extra nucleotides or detectable labels to the disclosed nucleotide sequence (SEQ ID NO: 1) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[2] for example, at page 34, line 18 through page 35, line 13 (describing fusion peptide molecules encoded by the claimed nucleic acid molecules), page 18 lines 1-5 (describing sequences with labels to facilitate detection), page 60, lines 3-27 (describing site-directed mutagenesis), page 18, line 9 through page 19, line 18 (describing appropriate hybridization conditions for the claimed nucleic acid molecules), and page 81, lines 11-19 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules).

Moreover, the court determined, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 U.S.P.Q.2d 1609, 1610 (Fed. Cir. 2002), that the written description inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art." *Enzo*, 296 F.3d at 1326-1327, 63 U.S.P.Q.2d at 1615. It is well established that

2 It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

claims "may be broader than the specific embodiment disclosed in a specification. *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In reRasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

(2) Applicants Have Described the Claimed Invention

The Final Action asserts "[T]he species specifically disclosed are not representative of the genus because the genus is highly variant." Final Action at page 5. The Examiner appears to assert that each nucleic acid molecule within the claimed genus must be described by its complete structure. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

In particular, Applicants have disclosed structural features, for example, the nucleotide sequence of SEQ ID NO: 1. The respective structural feature (the nucleotide sequence of SEQ ID NO: 1) is shared by every nucleic acid molecule in the claimed genus, and it distinguishes the members of the claimed genus from non-members. For example, if a nucleic acid molecule such as an mRNA is capable of hybridizing to a nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules capable of specifically hybridizing to a nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1.[3] If a nucleic acid molecule is not capable of hybridizing to a nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1, then it is not a member of the claimed genus. The

3 The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule such as an mRNA contains a nucleic acid molecule having 90% identity to a nucleic acid sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence having 90% identity to a nucleic acid sequence of SEQ ID NO: 1. *See* claim 8.

presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either hybridizes to a nucleic acid molecule having the nucleotides of SEQ ID NO: 1 or it does not. One skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains the recited nucleotide sequence. Thus, claims 2-3 and 8-11 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

The Examiner also argues that "[n]either the specification nor the claims disclose any structure-function relationship." Final Action at page 5. Applicants are aware of no such requirement to satisfy written description under 35 U.S.C. § 112, first paragraph. To the contrary, the Federal Circuit, in *Moba B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320, 66 U.S.P.Q.2d 1429, 1438 (Fed. Cir. 2003), the Federal Circuit clarified that a "court should determine whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants and mixtures sufficient to demonstrate possession of the generic scope of the claims." *Moba* at 10, *citing Enzo Biochem, Inc. v. Gen-Probe, Inc.* 323 F.3d 956, 966, 63 U.S.P.Q.2d 1609, 1615 (Fed. Cir. 2002). The Federal Circuit also reiterated that "[t]he test for compliance with §112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filling." *Moba* at 10. Moreover, in the present case, Applicants have described the claimed nucleic acid molecules by "structural features commonly possessed by members of the genus that distinguishes them from others." *Eli Lilly* at 1568-69.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule is capable of specifically hybridizing to a nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1. Thus, the claims are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112.

C. The Claimed Nucleic Acids Have Legal Utility

Claims 1-3 and 8-11 were erroneously rejected under 35 U.S.C. § 101 as allegedly not supported by a "specific, substantial, and credible utility or by a well established utility." Final Action at page 2. The Examiner admits that the specification discloses that the nucleic acid molecules of the present invention, including "probes for assisting in the isolation of full-length cDNAs or genes which would be used to make protein and optionally further usage to make the corresponding antibodies, gene mapping, isolation of homologous sequences, detection of gene expression such as in Northern blot analysis, molecular weight markers, chromosomal markers,...for numerous other generic genetic engineering usages, expression, antibody production,...detection of expression, antibody production, Western blots, etc." Final Action at page 7. However, the Final Action asserts these utilities are not a "specific and/or substantial utility or a well-established utility." Final Action at page 7.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson.* The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip*, 185 F.3d at 1366, 51 USPQ.2d at 1702. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real

world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example, use to identify the presence or absence of a polymorphism, and use as a hybridization probe for expression profiling. *See, e.g.*, specification at page 56, line 25, through page 57, line 23 and at page 45, line 24, through page 56, line 24. Either of these utilities described alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including isolating full-length cDNAs or genes, gene mapping, detection of gene expression, and as molecular weight markers. *See* Final Action at page 7. Moreover, the specification also discloses additional utilities for the claimed nucleic acid molecules,[4] including use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,[5] and use as molecular markers.[6]

4 It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

5 It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest.

6 One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular

(a) Identifying the Presence or Absence of a Polymorphism

One of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 49, line 24 through page 56, line 24. The Examiner argues that this utility, like many of the asserted utilities, is not specific or substantial, *see, e.g.,* Final Action at page 7, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms using the claimed nucleic acid molecules is not a legal utility.

Many of the disclosed utilities in this case, including the detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates such utilities by asserting that these utilities are not "useful" because they are "generic in nature" and, allegedly, "[i]dentifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a 'real world' context or use." Final Action at page 8. However, the fact that, *e.g.*, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107.01 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself.

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markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

Information has been obtained about the gas.[7] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The Examiner suggests that these uses are not legal utilities because "...[n]either the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well-established for the compounds." Final Action at pages 8-9. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used to isolate nucleic acid molecules of other plants and organisms such as alfalfa, barley, *Brassica*, soybean, sunflower, *Phaseolus*, etc.[8] Specification at page 34, line 25 through page 35, line 13. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and thus has not met the burden of proof required to establish a utility rejection. *See In re Brana*,

7 For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

8 Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be isolated using a claimed nucleic acid molecule is the promoter of the gene corresponding to that claimed nucleic acid molecule. Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. Specification at page 47, line 18, through page 48, line 23. The Examiner denigrates that utility by asserting that it is not "specific to the nucleic acid(s) and/or protein(s) being claimed." Final Action at page 8. This is not correct. The claimed nucleic acid molecules are particularly useful, for example, to identify markers and isolate promoters in *Arabidopsis*. *See, e.g.*, specification at page 85 *et. seq.* (Example 1).

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose, *i.e.*, chromosome walks. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acid molecules. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter active in *Arabidopsis*. *See, e.g.*, specification at page 1, line 20 through page 2, line 2; page 23, lines 6-27; and Example 1 at

page 85, line 24, *et. seq*. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a better starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

The Final Action also appears to assert that the disclosed uses are legally insufficient because they are not "substantial" utilities. Final Action at pages 7-9. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). " 'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[9]

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an

9 *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

immediate benefit to the public because, *e.g.*, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Cf. Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 2107 at 2100-29. Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[10]

10 Examples of incredible utilities are given in MPEP § 2107.01 at page 2100-34, and include:

A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2107.02 at 2100-41.

Applicants have explicitly identified specific and substantial utilities, not only in the specification, but in Applicants' Response dated May 19, 2003, at page 13, for example. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 1 under 35 U.S.C. §101 is improper and should be reversed.

D. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claims 2-3 and 9-11 were erroneously rejected as not enabled by the specification, because the claimed

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an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 9. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

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Holly L. Prutz
(Registration No. 47,755)
David R. Marsh
(Registration No. 41,408)

ARNOLD & PORTER
555 Twelfth Street, NW
Washington, DC 20004-1206
202.942.5000 telephone
202.942.5999 facsimile

Of Counsel
Lawrence M. Lavin, Jr.
(Registration No. 30,768)
Thomas E. Kelley
(Registration No. 29,938)
Monsanto Company

APPENDIX A

1. A substantially purified nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1 or its complement.

2. A substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing to a second nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1 or its complement.

3. A substantially purified *Arabidopsis thaliana* protein encoded by a molecule of claim 2.

8. A substantially purified nucleic acid molecule, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 90% identity to a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

9. The substantially purified nucleic acid molecule according to claim 8, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 95% identity to a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

10. The substantially purified nucleic acid molecule according to claim 9, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 98% identity to a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

11. The substantially purified nucleic acid molecule according to claim 10, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 99% identity to a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.